EXHIBIT 11

White Paper

The 340B Drug Discount Program Grew to $124B in 2023

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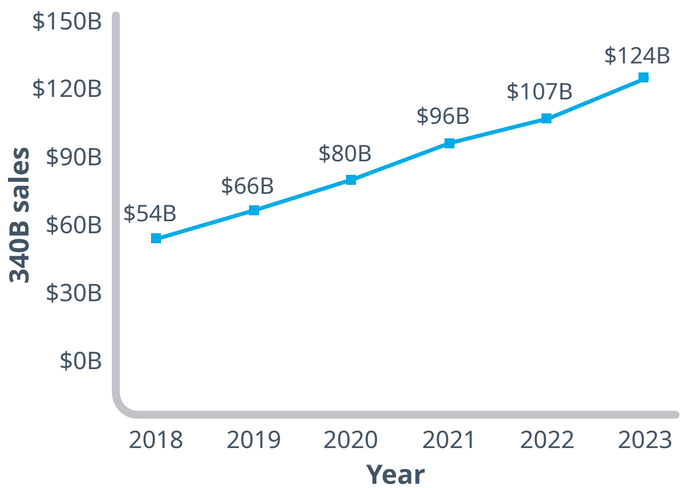
Abstract

This study is part of an ongoing series of annual reports on the size and growth of the 340B Drug Discount Program ("340B program"). In 2023, 340B sales were $124.1B in wholesale acquisition cost (WAC) dollars, representing year-over-year growth of 16.5%. Indexed to 2018, five year growth of the 340B program was 129.4%, more than triple the growth rate of non-340B sales. This was driven by 340B sales in hospitals and clinics which increased 18.9% year-over-year, up from 14.3% in 2022, and growth in the retail and mail channels of 10.2%, more than double its year-over-year growth of 3.9% in 2022, despite ongoing contract pharmacy restriction policies. Several factors have the potential to accelerate the future growth of the 340B program, including state bills prohibiting the use of manufacturers' contract pharmacy restriction policies, and the potential for eligibility expansion stemming from recent court findings.

Introduction

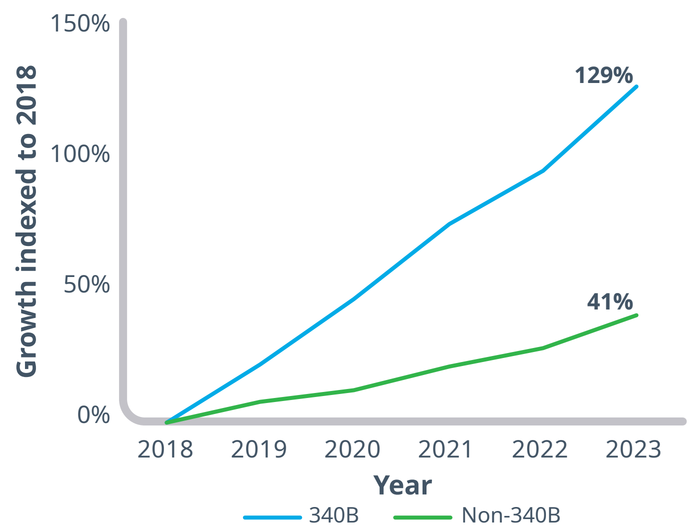
The 340B Drug Discount Program is a federal program in which qualifying hospitals and clinics receive Medicaid-like discounts from manufacturers on qualifying outpatient drugs. The 340B program continued to expand in 2023, reaching $124.1B in sales measured using wholesale acquisition cost (WAC) pricing, as shown in Figure 1. Expressed in terms of 340B discount pricing, this is $56.1B, meaning the average 340B discount is approximately 55%.

Figure 1. Annual growth of the 340B program, 2018 to 2023.



The growth of the program accelerated in 2023, with year-over-year 340B sales increasing 16.5%, up from 12% growth in 2022. In comparison, non-340B sales grew 10% year-over-year in 2023, up from 6% growth in 2022. To fully appreciate how rapidly the 340B program has grown in recent years, consider its sales indexed relative to 2018, as shown in Figure 2. From 2018 to 2023, non-340B sales grew 41.4%. During the same period, 340B sales grew 129.4%, *more than triple* the non-340B rate. Reasons for higher 340B growth include the increasing number of new specialty drugs that have been launched, many of which are prescribed or administered by physicians working in hospitals — the main participants in the 340B program — and the strong financial incentives that exist for hospitals and clinics to join the program or to maximize their 340B revenue once they have joined by strategies such as horizontal integration via the acquisition of community practices.

Figure 2. Cumulative year-over-year growth for 340B sales and non-340B sales indexed to 2018.

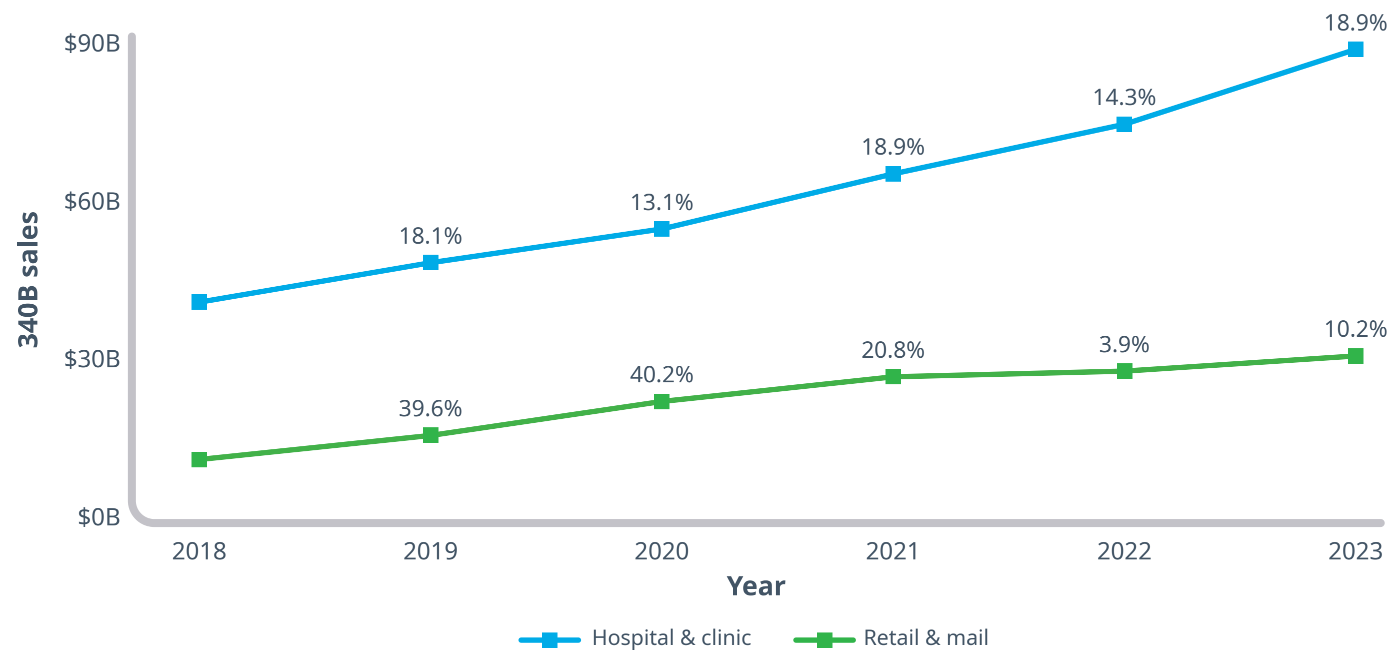


Impact of contract pharmacy restrictions

The majority of large manufacturers have implemented policies restricting the use of contract pharmacies[1], the first of which began in late 2020. Almost all contract pharmacy business exists in one of two distribution channels: retail — comprising chain pharmacies,

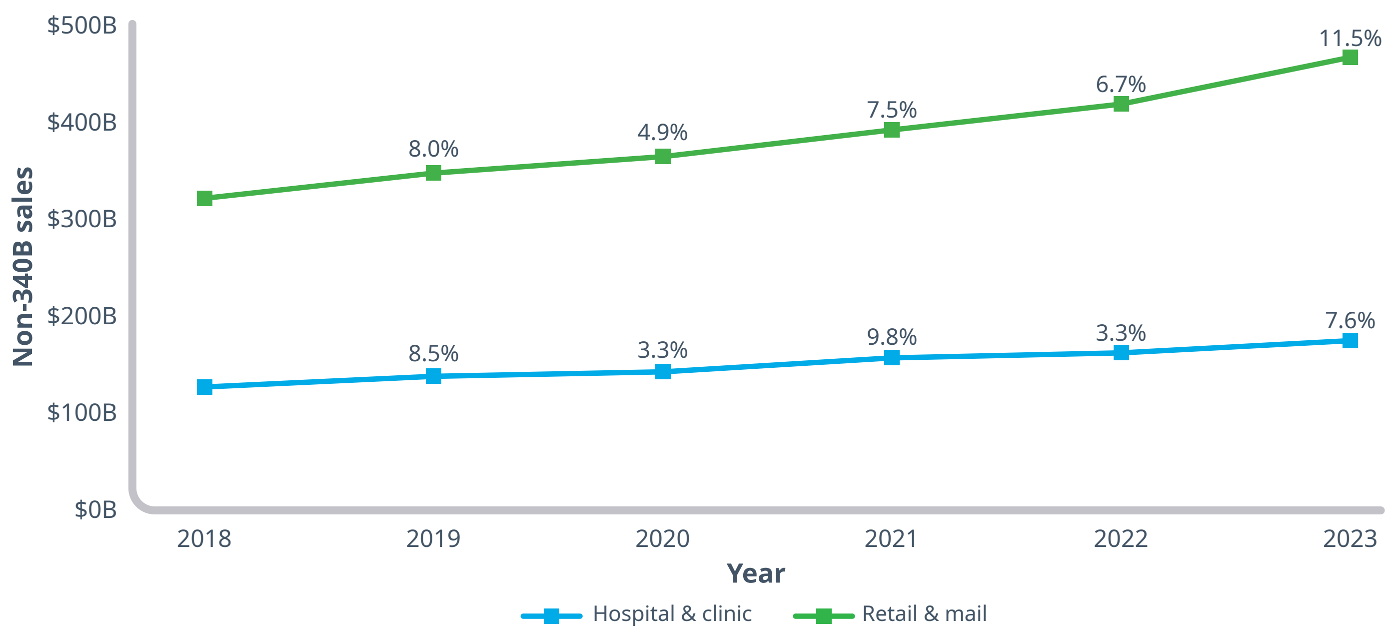
independent pharmacies, food stores, and mass merchandisers — and mail. Although the growth of 340B sales in retail and mail pharmacies flattened in 2021, 2022, and 2023, sales in hospitals and clinics accelerated during the same period, as shown in Figure 3. This suggests some 340B sales shifted from the retail and mail pharmacies to hospitals and clinics, due to a shift in where 340B patients filled prescriptions.

Figure 3. 340B sales by distribution channel. Data labels are year-over-year growth.



Non-340B sales showed the opposite trend, with sales in hospitals and clinics being relatively flat, while those in retail and mail pharmacies were growing more rapidly (Figure 4).

Figure 4. Non-340B sales by distribution channel. Data labels are year-over-year growth.



Disease areas

There was substantial variation in the 340B behavior of products across disease areas, measured using current 340B exposure (% of sales that are 340B), 340B year-over-year growth, and 340B revenue (the difference between sales at WAC versus the 340B discount price WAC), as shown in Figure 5 for the top 10 disease areas for total sales. They represented 39% of 340B sales in 2023 and fell into four segments.

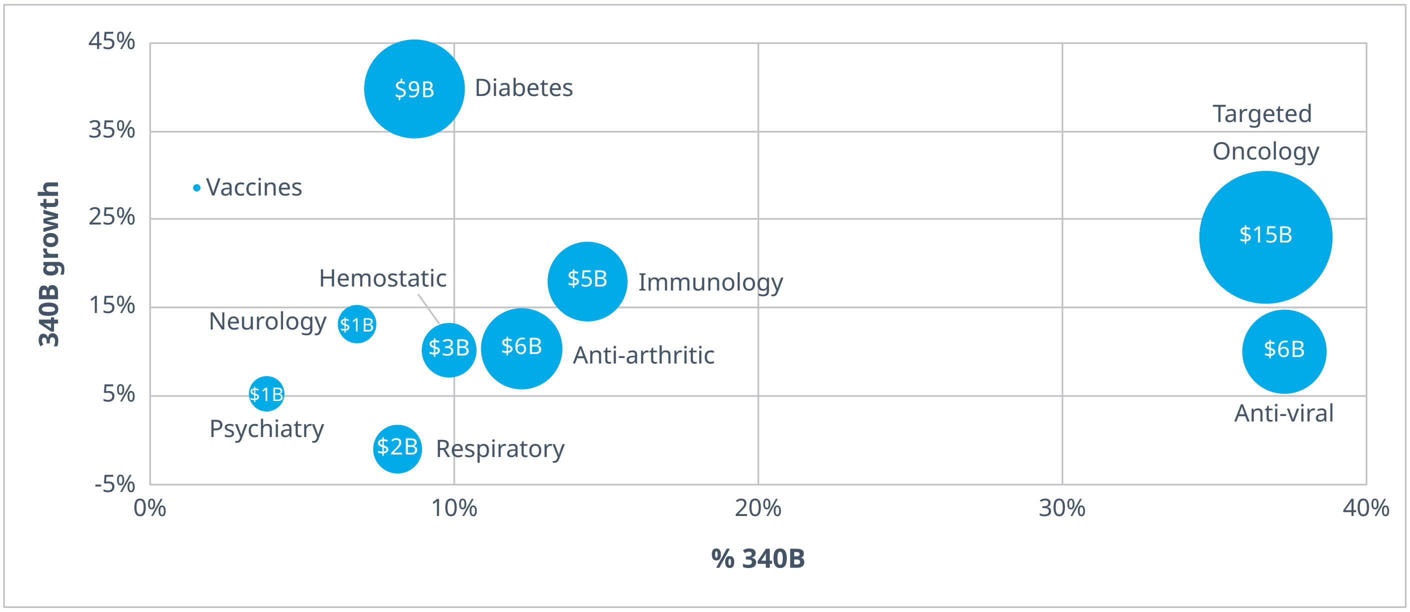
The first contained targeted oncology and anti-viral products, which had high 340B exposure of 35-36%, and moderate to high 340B growth of 10-23%. Their average 340B discount was 40-41% (not shown), and their combined 340B revenue in 2023 was $21.5B. The 340B program has a large impact on the gross to net behavior of these products. Many oncologists work at hospitals, which are the main participants in the 340B program, and there has been a large number of new and innovative oncology products. Anti-viral products treat HIV and hepatitis-C, and low socioeconomic status increases the risk of infection for both of these conditions[2-4], meaning that 340B exposure is high.

The second segment contained products that treat psychiatric conditions and respiratory diseases, which have a low 340B exposure (5-8%) and low 340B growth (0-5%). Although they have relatively high average 340B discounts (64-68%), they contributed only $3.2B in 340B revenue for 2023. The 340B program has a much lower impact on the gross to net of these products.

The third segment contained four groups: neurological products, hemostatic modifiers, anti-arthritics, and immunological agents. These groups were characterized by low to medium 340B exposure (7-16%), medium 340B growth (10-18%), and medium to high 340B discounts (48-76%). The combination of medium growth and larger 340B discounts is increasing the impact of the 340B program on the gross to net of this segment.

The final segment contained only one disease area — diabetes — but it has a large number of drugs and very high total sales. Despite its relatively low 340B exposure, its high 340B growth of 40%, and very high average 340B discount of 82%, mean the 340B program is having a growing impact on its gross to net. Product groupings include insulins, for which manufacturers have already

Figure 5. Year-over-year 340B growth versus percent 340B sales for the 10 largest USC2 disease areas. The area of the bubble indicates 340B revenue based on WAC.



taken pre-emptive action to lower prices[5,6] and GLP-1s, which are being used not only for diabetes but also for associated conditions such as obesity and heart disease.

Vaccines, sometimes called "biologics" in the Uniform System of Classification (USC) level 2[7], include products to treat influenza and COVID-19, are generally not eligible for 340B pricing, and had only 2% 340B exposure and 1% average 340B discounts.

The rapid growth of sales in the diabetes segment was driven mostly by GLP-1 products, and to a lesser extent by non-insulins, including SGLT2 inhibitors and DPP-4 inhibitors, as shown in Figure 6. Growth for insulin products was lower.

Anti-obesity drugs, some of which are types of GLP-1s, have also seen high 340B growth and are included for comparison.

Methods

Data sources

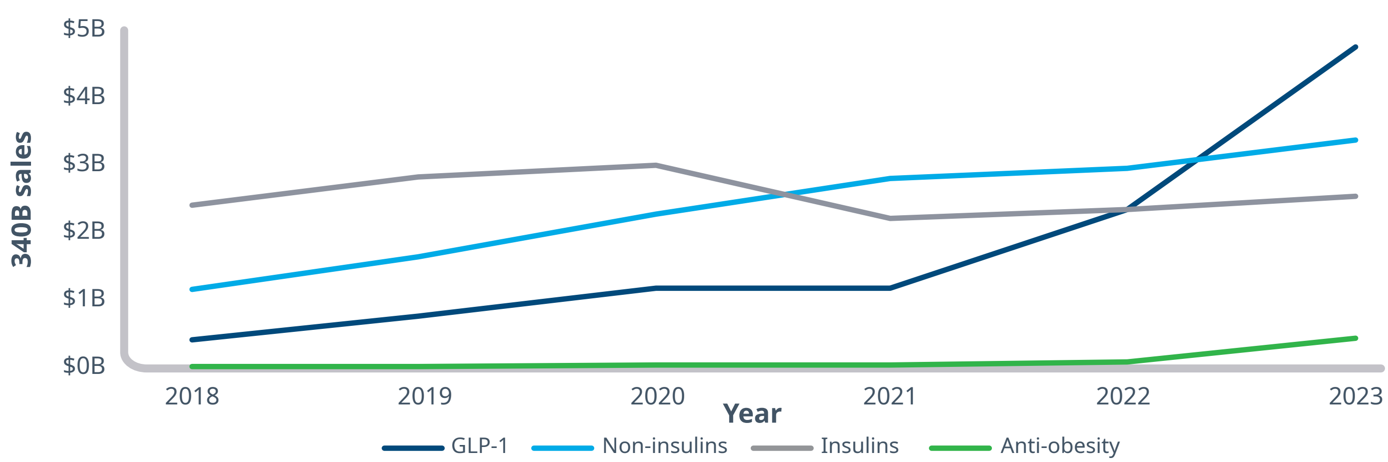
Sales data was sourced from IQVIA's DDD Subnational Sales database. Data spanned 2018 through 2023 and included all disease areas, specialty and non-specialty products, branded drugs and generics, prescription and over-the-counter products, and all distribution channels. Sales were expressed using WAC pricing at the product/pack level, while growth statistics were calculated as year-over-year percentage changes for the calendar year using dollarized sales. Estimates of the size of the U.S. pharmaceutical market reported in this report may differ versus those reported elsewhere in the literature. For example, sales were dollarized using WAC pricing which does not reflect the impact of manufacturer rebates nor the impact of 340B discounts. Also, sell-in was used to estimate sales in the mail distribution channel, and the data in DDD was not projected.

Pharmaceutical products were grouped into disease areas using USC2 groupings which define approximately 70 therapeutic categories.

Distribution channels were defined as retail (chain pharmacies, independent pharmacies, food stores, and mass merchandizers), mail/specialty mail, hospitals, and clinics. Three additional channels — long-term care, miscellaneous, and plan — which together represent less than 2% of 340B sales — were omitted from channel breakouts. "Hospitals" includes outpatient departments, clinics, and pharmacies owned by a hospital, and "clinics" refers to groups of physicians located at the same address and includes non-hospital 340B clinics. Contract pharmacy 340B volume is contained in the retail and mail channels.

The average 340B discount was estimated by comparing invoice price data to WAC pricing for 340B sales.

Figure 6. 340B sales for product groups in the diabetes USC2 disease area. Anti-obesity products are shown for comparison.



Discussion

At the time of publishing, 22 states had introduced or passed state bills aiming to prohibit the use of contract pharmacy restriction policies: Massachusetts, Rhode Island, New York, Maryland, Virginia, West Virginia, Kentucky, Florida, Michigan, Illinois, Mississippi, Louisiana, Arkansas, Missouri, Iowa, Nebraska, Kansas, Oklahoma, Idaho, Utah, Arizona, and Oregon. If a substantial number of states pass such policies, it could further accelerate 340B growth in the coming years. It will also reignite the problem of duplicate discounts, since it is difficult to determine the 340B status of prescriptions that are filled at contract pharmacies.

Another potential accelerator of 340B growth is eligibility expansion: the idea that 340B providers could create their own rules for which individuals are their patients and which prescriptions can be converted to 340B. In November 2023, the U.S. District Court of South Carolina found in favor of Genesis Health Care, Inc. concerning the question of 340B eligibility. HRSA had contended that it was necessary for the prescription for a 340B drug to have originated from an episode of care with Genesis or one of its contracted healthcare providers, or there was a referral for consultation[8]. This view aligns with guidance issued by HRSA in 1996 called the “patient definition”[9]. The court found HRSA’s definition for a “patient” is unnecessarily restrictive and the only requirement for a person to be 340B eligible is they’re a patient of the covered entity.

If this interpretation were to be implemented by other 340B hospitals and clinics, the 340B program could expand dramatically, possibly doubling in size[10].

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